

**“Unofficial” CN Orange Book user guide for pharmaceutical patents (Oct 2021 ver.)**

**Abstract**

The equivalence of the US Orange Book in China, the “CN Orange Book” has been operating since 29 June 2021. This “CN Orange Book” is a mountain full of treasures, for example clear indication on what claim is covering which subject matter in a particular drug patent. This “unofficial” user guide aims to provide foreigners information on how to navigate this “CN Orange Book”, which operates in Chinese.

**“Unofficial” CN Orange Book user guide for pharmaceutical patents (Oct 2021 ver.)**

In the US, the Orange Book is a publication from the US FDA that identifies drug products with marketing approval from the FDA and related patent and exclusivity information. Information in the Orange Book could be used in actions under the Hatch-Waxman Act, which allows a patentee to file an artificial act of infringement that allows the drug innovator to file suit before the generic drug is commercialized, such that the drug marketing approval process of the generic drug at the US FDA could be suspended.

China is required to introduce a similar system under the Phase-I trade agreements signed with the US in January 2020. I have been following this since then, and have several articles and posts on this topic. Recently, this “CN Orange Book” (official name: China listed drugs patent information registration platform) has become officially online on 29 June 2021, with many developments thereafter, and I have received many questions on how to use this. This motivates me to write this “unofficial” user guide, mainly for foreign users. This user guide may need updates periodically as things are changing too fast in China.

The equivalence of the US FDA in China is the China National Medical Products Administration, the NMPA.

This is the October 2021 version of this guide, as there have been many developments shortly after my first July version was finished on 19 July 2021.

## **Available to anyone, but could only search in Chinese**

The “CN Orange Book” is available at <https://zldj.cde.org.cn/home>. Anyone can access information therein. Below is a screen shot of the first page showing different functions thereon:

The screenshot shows the homepage of the China Patent Information Registration Platform. The header includes the site name '中国上市药品专利信息登记平台' and a '点击登录' (Click to login) button. The main banner features the title '中国上市药品专利信息登记平台' and a search bar with labels for '药品名称' (Drug Name), '专利号' (Patent No.), and '药品企业名称' (Drug Company Name). Below the search bar are three main service tiles: '专利登记' (Patent Registration), '专利信息公示' (Patent Information Publicity), and '专利声明' (Patent Certification). Each tile has an icon and a brief description. Below these tiles is a '通知公告' (Notice) section with a list of recent announcements and a '更多 >>' link.

中国上市药品专利信息登记平台 点击登录

# 中国上市药品专利信息登记平台

药品名称 专利号 药品企业名称

请输入药品名称

**专利登记**  
PATENT REGISTRATION

For registering drug patent information onto the platform

**专利信息公示**  
PATENT INFORMATION PUBLICITY

For searching drug patent information already registered

**专利声明**  
PATENT CERTIFICATION

For searching declarations filed by generic drug applicant against a particular drug

**通知公告** 更多 >>

- 国家药监局关于实施《药品专利纠纷早期解决机制实施办法（试行）》相关事宜的通告（2021年第46号）
- 关于结束中国上市药品专利信息登记平台测试工作的预通知
- 关于药品专利纠纷早期解决机制相关专利信息登记平台公开测试等有关事项的通知

For searching drug patent information already registered, the information is divided into three tabs, each respectively directed to Chinese medicine, chemical drug, and biological drugs as shown below (with the tab of chemical drugs chosen):

中国上市药品专利信息登记平台

Chinese medicine    Chemical drugs    Biological drugs

当前位置: 首页 > 专利信息公示列表 > 化药专利信息公示列表

中药专利信息公示    化药专利信息公示    生物制品专利信息公示

药品名称:  批准文号/注册号:

规格:  剂型:

Q 查找

| 序号 | 批准文号/注册号      | 药品类型 | 药品名称      | 规格                   | 剂型  | 操作 |
|----|---------------|------|-----------|----------------------|-----|----|
| 1  | 国药准字J20190024 | 化学药品 | 盐酸芬戈莫德胶囊  | 0.5mg (按C19H33NO2计)  | 胶囊剂 | 查看 |
| 2  | 国药准字J20190002 | 化学药品 | 沙库巴曲缬沙坦钠片 | 以沙库巴曲缬沙坦计100mg(...   | 片剂  | 查看 |
| 3  | 国药准字J20190001 | 化学药品 | 沙库巴曲缬沙坦钠片 | 以沙库巴曲缬沙坦计50mg(...    | 片剂  | 查看 |
| 4  | 国药准字J20180077 | 化学药品 | 利伐沙班片     | 20 mg                | 片剂  | 查看 |
| 5  | 国药准字J20180076 | 化学药品 | 利伐沙班片     | 15 mg                | 片剂  | 查看 |
| 6  | 国药准字J20180075 | 化学药品 | 利伐沙班片     | 10 mg                | 片剂  | 查看 |
| 7  | 国药准字J20180021 | 化学药品 | 利司那肽注射液   | 10µg剂量注射笔 (绿色) : ... | 注射剂 | 查看 |
| 8  | 国药准字J20180020 | 化学药品 | 利司那肽注射液   | 20µg剂量注射笔 (深紫红色...   | 注射剂 | 查看 |
| 9  | 国药准字J20171054 | 化学药品 | 沙库巴曲缬沙坦钠片 | 以沙库巴曲缬沙坦计100mg(...   | 片剂  | 查看 |

共 448 条    10条/页    < 1 2 3 4 5 6 ... 45 >    前往 1 页

Searches could be done and directed to the drug name, the format of the drug, dosage, and the drug marketing number at the NMPA. Mostly the name of the drug is used. Partial search for drug patent information already registered is available, but could only be done in Chinese. For example, using only the last three words of Palbociclib in Chinese (“柏西利” in “哌柏西利”) resulted in the following search results:

药品名称:  批准文号/注册证号:

规格:  剂型:

| 序号 | 批准文号/注册证号 | 药品类型 | 药品名称   | 规格    | 剂型  | 操作                                |
|----|-----------|------|--------|-------|-----|-----------------------------------|
| 1  | H20180042 | 化学药品 | 哌柏西利胶囊 | 100mg | 胶囊剂 | <input type="button" value="查看"/> |
| 2  | H20180041 | 化学药品 | 哌柏西利胶囊 | 75mg  | 胶囊剂 | <input type="button" value="查看"/> |
| 3  | H20180040 | 化学药品 | 哌柏西利胶囊 | 125mg | 胶囊剂 | <input type="button" value="查看"/> |

共 3 条 10条/页 < 1 > 前往 1 页

**Extensive information contained therein – good for FTO research**

The “CN Orange Book” has the following number of entries as of different dates in the table below:

| Type of drugs     | 30 June 2021 no. | 19 July 2021 no. | 3 October 2021 no. |
|-------------------|------------------|------------------|--------------------|
| Chinese medicines | 30               | 143              | 243                |
| Chemical drugs    | 278              | 448              | 532                |
| Biological drugs  | 39               | 60               | 78                 |

There was a relatively big surge in July 2021, shortly after the database was firstly introduced on 29 June 2021, while the number of registrations slowed down significantly thereafter. This could be expected, as every drug owner would rush into the register at the beginning.

One amazing feature of the “CN Orange Book” is the inclusion of extensive data in each entry. Below is a screenshot of the entry in the “CN Orange Book” for the drug Palbociclib capsule 125mg (Note: only part of the entries of one of the three patents registered for this drug is shown below due to limit of the screen shot that could be taken):

专利信息登记详情

相关专利号: ZL03802556.6 CN patent no. 专利名称: 2-(吡啶-2-基氨基)-吡啶并[2,3-d]嘧啶-7-酮

专利权人: 沃尼尔·朗伯有限责任公司 专利被许可人:

专利授权日期: 2011-06-22

授权证明文件: 文件1: CN03802556.6\_专利证书.pdf  
文件2: CN03802556.6授权文本.pdf click to instantly download CN grant publication

上市许可持有人与专利权人的关系: 普通实施许可合同的被许可人

药品与相关专利权利要求的对应关系:

| 序号 | 权利要求编号 | 专利类型          | 专利保护期届满日   | 状态 | 备注                                |
|----|--------|---------------|------------|----|-----------------------------------|
| 1  | 1-2    | 化学药品活性成分化合物专利 | 2023-01-09 | 有效 | 权利要求编号是按本专利无效宣告请求审查决定中维持有效的权利要求编号 |
| 2  | 3      | 化学药品医药用途专利    | 2023-01-09 | 有效 | 权利要求编号是按本专利无效宣告请求审查决定中维持有效的权利要求编号 |
|    |        |               |            |    | 权利要求编号是按本专利无效宣告                   |

It can be seen that in addition to the patent number, the following information in the “CN Orange Book” database entries is also available:

- 1) The granted patent itself is available for downloading at a link on the same page.
- 2) The claim number(s), and the relevant subject matter, are clearly identified.
- 3) The full-term expiry of the patent(s) is clearly identified.
- 4) Whether the patent has survived through invalidation is also specified in the note section.

On the other hand, there exists entries without the above extensive information of 1)-4), as shown below as of 19 July 2021:

专利信息登记详情

---

**专利信息**

相关专利号: ZL03821144.0      专利名称: 包含盐酸伐地那非三水合物的药物

专利权人: 拜耳知识产权有限责任公司      专利被许可人:

专利授权日期: 2010-12-15

授权证明文件: [文件1: 伐地那非片-ZL03821144.0-专利证书.pdf](#)  
[文件2: 伐地那非片-ZL03821144.0-法律状态.pdf](#)  
[文件3: 伐地那非片-ZL03821144.0-说明书权利要求书摘要.pdf](#)

上市许可持有人与专利权人的关系: 普通实施许可合同的被许可人

药品与相关专利权利要求的对应关系:

| 序号 | 权利要求项编号 | 专利类型 | 专利保护期届满日 | 状态 | 备注 |
|----|---------|------|----------|----|----|
| 1  |         |      |          |    |    |

---

**上市许可持有人联系信息**

境内联系人: 刘红强      境内联系电话: 010-65893290

× 关闭

The same entry above has its information updated as of 3 October 2021, indicating claims 5 to 8 of the relevant patent CN ZL03821144.0 are directed to the drug composition containing the active pharmaceutical ingredient API vardenafil hydrochloride trihydrate:

专利信息登记详情

相关专利号: ZL03821144.0      专利名称: 包含盐酸伐地那非三水合物的药物

专利权人: 拜耳知识产权有限责任公司      专利被许可人:

专利授权日期: 2010-12-15

授权证明文件: 文件1: 伐地那非片-ZL03821144.0-说明书权利要求书摘要.pdf  
文件2: 伐地那非片-ZL03821144.0-专利证书.pdf  
文件3: 伐地那非片-ZL03821144.0-法律状态.pdf

上市许可持有人与专利权人的关系: 普通实施许可合同的被许可人

药品与相关专利权利要求的对应关系:

| 序号 | 权利要求项编号 | 专利类型             | 专利保护期届满日   | 状态 | 备注 |
|----|---------|------------------|------------|----|----|
| 1  | 5-8     | 化学药品含活性成分的药物组合专利 | 2023-07-03 | 有效 |    |

上市许可持有人联系信息

境内联系人: 刘红强      境内联系电话: 010-65893290

↑  
**Updated patent claim information**

× 关闭

It should be noted that the relevant regulations, the NMPA Measures (see below) put the onus on the patentee/drug marketing approval holder DMAH to ensure the accuracy of the information registered on the platform, which requires the claim(s) covering what aspect of the drug to be identified (Article 4 of the NMPA Measures). Failure to do so could be legally liable (Article 15 of the NMPA Measures), while it is unclear what exactly are the punishments.

Most of the entries in the “CN Orange Book” contain extensive information like the one of Palbociclib capsule 125mg above (if not, updated could be expected). Such information could be very useful for a freedom-to-operate (FTO) exercise. The immediate availabilities of the grant patent publication and the full-term expiry are already very useful. The specific identifications of the claim(s) and relevant subject matter are even more so.



By contrast, the equivalent FDA records only contain the US patent numbers and the full term expiry date, but nothing further. Below is the screenshot of Palbociclib capsule 125mg in the US FDA Orange Book records:

Patent and Exclusivity for: N207103

| Product 003<br>PALBOCICLIB (IBRANCE) CAPSULE 125MG |           |                   |                |              |                 |                  |                 |  |
|--|-----------|-------------------|----------------|--------------|-----------------|------------------|-----------------|--|
| Patent Data  |           |                   |                |              |                 |                  |                 |  |
| Product No   | Patent No | Patent Expiration | Drug Substance | Drug Product | Patent Use Code | Delist Requested | Submission Date |  |
| 003  | 8938612   | 01/16/2023        | DS             | DP           |                 |                  | 02/26/2015      |  |
| 003  | 7208489   | 01/16/2023        | DS             | DP           |                 | Y                | 02/26/2015      |  |
| 003  | 7456168   | 01/16/2023        |                |              | U-1998 U-2515   |                  | 02/26/2015      |  |
| 003  | 10723730  | 02/08/2034        | DS             | DP           |                 |                  | 08/27/2020      |  |
| 003  | RE47739   | 03/05/2027        | DS             | DP           |                 |                  | 12/19/2019      |  |

  

| Exclusivity Data                        |                  |                        |
|---|------------------|------------------------|
| Product No                              | Exclusivity Code | Exclusivity Expiration |
| Your search did not return any results. |                  |                        |

### Restrictions on the type of patents that could be registered

The “CN Orange Book” restricts that only the following types of patents could be registered for the respective drugs (Articles 5 and 12 of the NMPA Measures):

- Chemical drugs – chemical compound of the active ingredient; composition comprising the active ingredient; medical use
- Biological drug – sequence structure of the active ingredient; medical use
- Chinese medicine – composition; extracts from Chinese medicine; medical use

While not specified in the articles of the NMPA measures, the accompanying explanations of the NMPA measures specify that patents covering intermediates, metabolites, crystal form, method of manufacturing and testing methods are **not** considered as relevant patents under the patent linkage system, i.e. these patents should not be registered on the “CN Orange Book”. Therefore, the above types of patents would not be seen in the “CN Orange Book”.

Having said so, one way to get around the restriction on crystal form is to record a patent having a composition claim, or medical use claims (in the form of Swiss-type claim, as method of treatment is not patentable in China) containing the crystal form of the API. An example will be shown below in the first contentious drug patent linkage declaration.

## **Only Chinese company could register, and make entries on the platform**

While everyone could access the platform to view information therein, in order to register entries on the platform (either for a drug, or making a declaration against a drug), one must register as a user on the platform. However, only a Chinese company could do so, as it is required to input the so-called "unified social credit codes" (compulsory) during registration, which are available to all Chinese companies. Further, the registration requires a CN mobile number to complete (for receiving a confirmatory text message). See the screenshot below:

全国一体化在线政务服务平台  
国家药品监督管理局网上办事大厅 V2.0  
法人注册

1 填写认证信息      2 创建用户      3 完成注册

\* 法人名称: 请输入您的法人名称 (企业/事业单位/社会组织名称)

\* 法人类型: 请选择法人类型

\* 统一社会信用代码: 请输入法人统一社会信用代码 **Unified social credit code**

\* 法定代表人: 请输入法定代表人姓名

\* 法定代表人证件类型: 请选择法定代表人证件类型

\* 法定代表人证件号码: 请输入法定代表人证件号码

\* 法定代表人手机号: 请输入法定代表人手机号(中国大陆手机号) **CN mobile number**

\* 图形验证码: 请输入右侧图形验证码, 再获取短信验证码

\* 短信验证码: 请输入收到的短信验证码 **获取短信验证码**

我已阅读并同意《政务服务大厅注册协议》

开始认证

## **Declaration from a generic drug applicant against an innovative drug**

For details on how such a declaration works, please refer to my articles below:

<https://www.linkedin.com/pulse/cn-patent-inkage-measures-trial-finalized-issued-nmpa-toby-mak> (This article talks about the finalized NMPA measures, which is based on the draft measures below)

<https://www.linkedin.com/pulse/cn-drug-patent-registration-system-orange-book-opened-toby-mak> (This article talks about the draft NMPA measures)

As a summary, when a generic drug applicant applies for drug marketing approval at the NMPA, the generic drug applicant is required to make a declaration of any one of the following four types:

- I) That there is no patent information registered related to the drug.
- II) That the patent(s) has already expired, or been declared invalid.
- III) The date on which the patent(s) will expire, and that generic applicant promises that the generic drug will not go on the market until the expiry of the patent(s).
- IV) That the patent(s) is not infringed, or should be declared invalid.

As of 3 October 2021, 410 declarations have been announced on the CN platform, with vast majority being type I) to III) declarations. The first type III) declaration was announced on 9 July 2021, with the screen shot below:

专利声明详情

申请人: 北京泰德制药有限公司  
联系人: 张雨山  
电子邮箱: zhangysh3@tidepharm.com  
通讯地址: 北京市北京经济技术开发区科创八街19号院  
联系电话: 010-67880648-1524

被仿制药等相关信息

药品名称: 脉柏西利胶囊 Name of drug  
持有人名称: Pfizer Europe MA EEIG Owner's name  
批准文号/注册证号: H20180040 Innovative drug registration no.

| 序号 | 登记的专利号           | 登记的权利要求项编号 | 专利声明类型 | 备注 |
|----|------------------|------------|--------|----|
| 1  | ZL201010255766.6 | 1-4,5-6,9  | 3类     |    |
| 2  | ZL201110115074.6 | 1-2        | 3类     |    |
| 3  | ZL03802556.6     | 1-2,3,4    | 3类     |    |

专利声明类型: 1类: 中国上市药品专利信息登记平台中没有被仿制药相关专利信息 (专利信息登记平台登记号、登记的专利号均填写“无”); 2类: 中国上市药品专利信息登记平台收录的被仿制药相关专利权已终止或者被宣告无效, 或者仿制药申请人已获得专利权人相关专利实施许可 (在备注中注明相应的具体情形); 3类: 中国上市药品专利信息登记平台收录有被仿制药相关专利, 仿制药申请人承诺在相应专利权有效期届满之前所申请的仿制药暂不上市; 4.1类: 中国上市药品专利信息登记平台收录的被仿制药相关专利权应当被宣告无效, 4.2类: 仿制药未落入中国上市药品专利信息登记平台收录的被仿制药相关专利权保护范围。

Declaration type 4.1 - the patent(s) should be declared invalid  
Declaration type 4.2 - the generic drug does NOT fall within the scope of the patent(s)

× 关闭

The key is the type of declaration filed, in the screen shot above being type III). It should also be noted that this page subdivides Declaration type IV) into the following two types:

- 4.1 - The patent(s) should be declared invalid.
- 4.2 – The generic drug does not fall within the scope of the patent(s).

The type of the declaration determines whether the drug patentee/DMAH could take action against the subject generic drug marketing approval application. It appears only action could be taken against declaration type 4.2 (the generic drug does not fall within the scope of the patent(s)). While Article 7 of the NMPA measures could be literally read as allowing complaints to be filed at a court or the CNIPA for all 4 types of declarations, when combining with the relevant measures of the Supreme People's Court and the CNIPA, it appears that there is a typographical error in Article 7 of the NMPA measures, and complaint could only be filed for declaration type 4.2.

Type 4.1 declaration has already been announced, with an example shown below:

The screenshot shows a patent declaration form titled "专利声明详情" (Patent Declaration Details). The form is categorized under "化学仿制药/中药同名同方药/生物类似药信息" (Chemical generic drugs/Chinese medicine with same name and formula/biologics similar drug information). The form contains the following information:

- 药品名称:** 替格瑞洛片 (Ticagrelor tablets)
- 剂型:** 片剂 (Tablets)
- 申请人:** 山西德元堂药业有限公司 (Shanxi Deyuantang Pharmaceutical Co., Ltd.)
- 药品类型:** 化学药品 (Chemical drug)
- 规格:** 90mg
- 通讯地址:** 山西省晋中市山西示范区晋中开发区汇通产业园区开发区机械园 (Huitong Industrial Park, Jinzhong Development Zone, Jinzhong, Shanxi Province)
- 联系电话:** 0354-3072288-805
- 联系人:** 段陈平 (Duan Chenping)
- 电子邮箱:** dcp207@126.com
- 被仿制药等相关信息:**
  - 药品名称:** 替格瑞洛片 (Ticagrelor tablets)
  - 批准文号/注册证号:** 外包装注册证号: H20171080/小包装注册证号: H20171079
- 持有人名称:** AstraZeneca AB

At the bottom of the form, there is a table with the following data:

| 序号 | 登记的专利号 | 登记的权利要求项编号 | 专利声明类型 | 备注 |
|----|--------|------------|--------|----|
| 1  | 无      | 无          | 4.1类   | 无  |

The form also includes a "关闭" (Close) button at the bottom right.

In the above, the drug at issue is ticagrelor 90mg tablet, with AstraZeneca being the DMAH, and the generic drug applicant being Shanxi Deyuantang Pharmaceutical Co.,Ltd. (Deyuantang). In this situation, there is nothing AstraZeneca could do to delay the drug marketing approval process of the generic ticagrelor 90mg tablet from Deyuantang at the NMPA.

### **The first type 4.2 declaration**

This was announced on 23 July 2021 directed to the drug dapagliflozin (达格列净) 5 and 10 mg, with AstraZeneca as the DMAH in China. The relevant screen shot for the 5mg drug is shown below, while that of the 10 mg drug has similar contents.

专利声明详情

药品名称: 达格列净片      药品类型: 化学药品  
 剂型: 片剂      规格: 5mg  
 申请人: 江苏豪森药业集团有限公司      通讯地址: 连云港经济技术开发区东晋路9号  
 联系人: 王瑞军 李琴      联系电话: 13951499819 0518-83099366  
 电子邮箱: 13951499819@163.com liq1@hspharm.com

被仿制药等相关信息

药品名称: 达格列净片      批准文号/注册证号: H20170117、H20170118  
 持有人名称: AstraZeneca AB

| 序号 | 登记的专利号            | 登记的权利要求编号           | 专利声明类型 | 备注            |
|----|-------------------|---------------------|--------|---------------|
| 1  | ZL 200910158686.6 | 1, 2, 3, 14, 15, 16 | 3类     |               |
| 2  | ZL 200880016902.7 | 8                   | 4.2类   | 组合物的API与该专利不同 |
| 3  | ZL 201210201489.X | 1, 2, 3, 7, 8, 9    | 4.2类   | 组合物的API与该专利不同 |
| 4  | ZL 200780024135.X | 9                   | 4.2类   | API与该专利不同     |

× 关闭

It is interesting to note that the generic drug applicant Jiangsu Hansoh Pharmaceutical Group Co., Ltd. (江苏豪森药业集团有限公司, Hansoh) filed a type III) declaration against CN200910158686.6 directed to the chemical compound of the API dapagliflozin itself, i.e. Hansoh undertakes that they would only put their drug onto the market after CN200910158686.6 has expired on 15 May 2023 (CN200910158686.6 is a divisional from CN03811353.8).

On the other hand, Hansoh filed type 4.2 declarations against the following 3 CN patents, i.e. Hansoh declared that their generic drug does not fall within the scope of the following 3 CN patents that are directed to specific formulations and medical uses:

- 1) CN200880016902.7 (full term expiry 21 March 2028) - specific formulation comprising the API in the form of dapagliflozin propylene glycol hydrate, microcrystalline cellulose, lactose, crospovidone, silicon dioxide, magnesium stearate, with each components presents in respective specific amounts (claim 8).
- 2) CN200780024135.X (full term expiry 21 June 2027) - Medical use (Swiss-type claim) of dapagliflozin propylene glycol hydrate with specific crystalline structure (note: as mentioned above patents directed to crystalline structure of a drug per se should not be registered in the CN Orange Book) in treating diabetes, insulin resistance, hyperglycemia, hyperinsulinemia, elevated blood levels of fatty acids or glycerol,

hyperlipidemia, dyslipidemia, obesity, hypertriglyceridemia, or diabetic complications (claim 9).

- 3) CN201210201489.X (full term expiry 21 March 2028) - specific formulation comprising the API in the form of dapagliflozin propylene glycol hydrate with a specific dosage regime (claim 1), with further components including bulking agent, binder, disintegrant, and so on (claims 2 and 3), and the medical uses of such specific formulation (Swiss-type claims) for treating diabetes.

For 2), it should be noted that the patent is in fact directed to the crystal form of the API in the form of dapagliflozin propylene glycol hydrate, and therefore the CN Orange Book registration is directed to the medical use in Swiss-type claim containing such specific crystal form. Therefore, for China, it is important to include at least one composition or medical use Swiss-type claim for drug crystal form patent.

According to the above, Hansoh chose to challenge the patents directed to specific formulations comprising the API dapagliflozin propylene glycol hydrate, and the medical use of the crystalline API. Comparing with the chemical compound patent CN200910158686.6 (which Hanson chose to deal with using a type III) declaration), there is higher chance to get around these formulation and medical use patents, for example by not using dapagliflozin propylene glycol hydrate, but uses dapagliflozin itself (whether this would be caught by equivalence is another question). In fact, Hanosh declared that the API in their generic drug is different from that in these 3 CN patents, i.e. dapagliflozin propylene glycol hydrate.

AstraZeneca had until 6 September 2021 (45 days from 23 July 2021) to file a complaint against Hansoh's type 4.2 declaration against the 3 CN patents above at the Beijing IP Court, or at the CNIPA. Failure to do so would result in that the drug marketing approval application would be processed as normal by the China National Medical Products Administration as usual, i.e. without any delay.

If AstraZeneca filed the complaint and was accepted (by the the Beijing IP Court, or the CNIPA), and a decision was made within 9 months from the date of acceptance of the complaint:

- if the decision was in favor of AstraZeneca, the drug marketing approval would be delayed to shortly before the expiry of the above three patents, i.e. maximum delay up to 2028.
- if the decision was not in favor of AstraZeneca or not within 9 months, the drug marketing approval would be processed as normal with no delay.

However, as Hanosh undertakes a type 3 declarations against CN200910158686.6, the earliest date that Hanosh could put their generic drug on the market in China is 15 May 2023.

I have tried to check whether AstraZeneca had filed the compliant at the Beijing IP Court the CNIPA by 6 September 2021, but no luck. In light of the relative ease of getting around the above three subject patents, and Hansoh undertakes that they would only put their drug onto the market after 15 May 2023, AstraZeneca may choose not to file the compliant against the type 4.2 declarations.

### **Conclusion**

While the “CN Orange Book” is based on the US Orange Book (as required under the US-CN trade agreements 2021), the Chinese system has the following characteristics:

- a) The patent information in the Chinese system is much more extensive than that of the US.
- b) There is no drug data exclusivity information in the Chinese system.
- c) Action could only be taken against type 4.2 declaration (the generic drug does not fall within the scope of the patent(s)) in China.

Regarding c), this may be the substantive difference of the CN system from the US system. In essence, in China, there is nothing the DMAH could do to delay the drug marketing approval process at the NMPA if the generic drug applicant simply alleges that the patent at issue should be declared invalid, and does not even challenge the validity of the patent afterwards.

There have been many changes on the “CN Orange Book” since its establishment on 29 June 2021. For example, in the very beginning, the platform does not have different tabs for entries of chemical drug, biological drug, and Chinese medicine. Now individual tabs

are available, making searching and counting much easier. Finally, all five types (types I to III), 4.1, and 4.1) declarations have been announced.

If you are an innovative drug owner, I am not surprised that you have already registered your drug patent information on the “CN Orange Book” to deter generic drug marketing approval application.

For others, including myself heavily involved in drug freedom-to-operate work, the “CN Orange Book” is a mountain full of treasures. Once the Chinese drug name is known (hint: have a look at the drug innovator’s Chinese website), the grant patent publication, claim(s) and subject matter(s) relevant (with clear indication on what claim is covering which subject matter), full term expiry, and invalidation information (if available) are all available in one place.

Author: Toby MAK, Tee & Howe Intellectual Property Attorneys ©2021